NOTICES OF EMERGENCY RULEMAKING

This section of the *Arizona Administrative Register* contains Notices of Emergency Rulemaking.

The Office of the Secretary of State is the filing office and publisher of these rules.

Questions about the interpretation of the emergency rules should be addressed to the agency proposing them. Refer to Item #5 to contact the person charged with the rulemaking.

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 18. NATUROPATHIC PHYSICIANS MEDICAL BOARD

Editor's Note: The following Notice of Emergency Rulemaking was exempt from Executive Order 2012-03 as issued by Governor Brewer, and submitted for publication in the Register while this order was still in effect. (See the text of the executive order on page 102.)

[R14-210]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**
R4-18-904 — Amend

2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statutes (specific):
Authorizing statute: A.R.S. § 32-1504(A)(1)
Implementing statute: A.R.S. § 32-1504 (A)(8).

3. The effective date of the rule:
December 18, 2014

a. If the agency selected a date earlier than the 60 day effective date as specified in A.R.S. § 1032(A), include the earlier date and state the reason or reasons the agency selected the earlier effective date as provided in A.R.S. § 41-1032(A)(1) through (5).
The agency has selected a date earlier than the 60 day effective date in order to quickly return the use of any of the four nutrients specified in R4-18-904(B)(2), while requiring compliance with the United States Food and Drug Administration, and the state Board of Pharmacy; pursuant to A.R.S. § 32-1501(15)(iii).

b. If the agency selected a date later than the 60 day effective date as specified in A.R.S. § 1032(A), include the later date and state the reason or reasons the agency selected the later effective date as provided in A.R.S. § 41-1032(B):
Not applicable

4. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of this Notice of Emergency rulemaking:
Notice of Rulemaking Docket Opening: 18 A.A.R. 1869, August 3, 2012
Notice of Proposed Rulemaking: 18 A.A.R. 1821, August 3, 2012

5. The agency's contact person who can answer questions about the rulemaking:
Name: Gail Anthony, Executive Director
Address: 1400 W. Washington, Suite 230
Phoenix, AZ 85007
Telephone: (602) 542-8242
Fax: (602) 542-8804
Email: gail.anthony@aznd.gov

6. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:
A.R.S. § 32-1504 (A)(8) States the Board shall adopt rules for the safe administration of intravenous nutrients, and identify and exclude substances that do not meet the criteria of nutrients suitable for intravenous administration.

A.A.C. R4-18-904(B)(1) identifies nutrients not suitable for intravenous administration as any substance not manufactured and supplied for intravenous use by a manufacturer registered with the United States Food and Drug Administration or compounded by a pharmacy licensed in Arizona, another state, or United States territory. The rule however goes further by establishing a list of four excluded nutrients in A.A.C. R4-18-904(B)(2); Silver protein, or any substance that contains silver, Cesium chloride, Hydrazine sulfate, and Lipid replacement as used in

total parenteral nutrition. A.R.S. § 32-1501(15)(iii) defines nutrients as a substance that provides nourishment for growth or metabolism and that is manufactured and supplied for intravenous use by a manufacturer registered with the United States Food and Drug Administration or compounded by a pharmacy licensed by the state Board of Pharmacy. Statute does not require rule to list specific nutrients because both statute and rule already define substances considered not suitable for intravenous administration.

It has come to the attention of the Board that some of our licensees have used one or more of the substances listed in A.A.C. R4-18-904(B)(2), and state they have had positive results with their use. The American Naturopathic Research Institute/Naturopathic Oncology Research Institute report, they are currently conducting an IRB (ID # IORG0007953), in which one or more of the excluded nutrients had been used. The current rules have an impact on the data supplied for the IRB. According to the website www.cancer.gov; The Food and Drug Administration (FDA) has approved the study of hydrazine sulfate in clinical trials. According to www.researchednutritionals.com; Lipid Replacement is not just the dietary substitution of certain lipids with proposed health benefits; it is the actual replacement of damaged cellular lipids with undamaged lipids to ensure proper structure and function of cellular structures, mainly cellular and organelle membranes. Removing the use of any of the four excluded substances may impact the health and safety of the public. The Board is requesting an emergency rule change under A.R.S. § 41-1032(A)(1). Also, the rule was not previously made as an emergency rule.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Board did not review or rely on any study.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact:

When used in the economic impact statement summary, annual cost/revenue are designated as minimal when less than $5,000, moderate when between $5,000 and $10,000, and substantial when greater than $10,000.

The Board will incur minimal expense to write the rules and enforce their requirements.

The elimination of R4-18-904(B)(2) should not result in any costs to a naturopathic physician, medical student, or medical assistant, as the removal should not cause extra burden on any licensee or certificate holder.

10. Any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. When applicable, matters shall include but are not limited to:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The Board issues a license or certificate, which falls within the definition of general permit.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Federal law is applicable to the subject of the rule. A.A.C. R4-18-904(B)(1) requires that nutrients for intravenous administration must be manufactured and supplied for intravenous use by a manufacturer registered with the United States Food and Drug administration. This provision is consistent with the requirements for registration in 21 U.S.C. § 360(b) (U.S. operations) and (i) (foreign establishments).

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

The Board did not receive such an analysis from any person.

11. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

There is no incorporation by reference document.

12. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments:

The Board received written notice from the State of Arizona Naturopathic Association (AzNMA) requesting review of the current rule. The Board received a letter from Attorney Steven C. Mahaffy in his capacity as Council representing licensee Dr. Colleen Huber, has also requested removal of the current rule's subsection (B)(2). The Board heard comments from Licensees and members of the public at the meeting of July 10, 2014 and September 11, 2014. All correspondence and comments are in favor of removing the rule's subsection (B)(2).

13. The date the Attorney General approved the rule:

December 17, 2014

14. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 18. NATUROPATHIC PHYSICIANS MEDICAL BOARD

ARTICLE 9. CERTIFICATE TO DISPENSE

Section
R4-18-904. Dispensing; Intravenous Nutrients

ARTICLE 9. CERTIFICATE TO DISPENSE

R4-18-904. Dispensing; Intravenous Nutrients

A. To prevent toxicity due to the excessive intake of a natural substance, drug, or device, before dispensing the natural substance, drug, or device to an individual, a certified physician shall:
1. Conduct a physical examination of the individual,
2. Conduct laboratory tests as necessary that determine the potential for toxicity of the individual, and
3. Document the results of the physical examination and laboratory tests in the individual's medical record.

B. For the purposes of A.R.S. § 32-1504(A)(8), a substance is considered a nutrient ~~not~~ suitable for intravenous administration if it ~~is:~~
~~1. Not manufactured and supplied for intravenous use by a manufacturer registered with the United States Food and Drug Administration or compounded by a pharmacy licensed in Arizona, another state, or United States territory; or~~
Complies with A.R.S. § 32-1501(15)(iii).
~~2. One of the following:~~
~~a. Silver protein, or any substance that contains silver;~~
~~b. Cesium chloride;~~
~~c. Hydrazine sulfate; or~~
~~d. Lipid replacement as used in total parenteral nutrition.~~